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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,298	04/20/2007	Fiona Becker	10582.204-US	1084

25908 7590 08/19/2010  
NOVOZYMES NORTH AMERICA, INC.  
500 FIFTH AVENUE  
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NEW YORK, NY 10110

EXAMINER
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BADR, HAMID R

ART UNIT	PAPER NUMBER
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1781

NOTIFICATION DATE	DELIVERY MODE
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08/19/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/588,298	<b>Applicant(s)</b> BECKER ET AL.	
	<b>Examiner</b> HAMID R. BADR	<b>Art Unit</b> 1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 14-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Applicants' amendment filed 5/24/2010 is acknowledged.

Claims 1-10 and 14-20 are being considered on the merits.

#### ***Claim Objection***

Claim 6 is objected to for not mentioning the species name. *Paenibacillus* DSM 16232 should be written to include the species name. The instant specification designates *Paenibacillus pabuli* as the species name. Correction is required.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-10 and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sibbesen et al. (WO 03/020923; hereinafter R1) in view of Cherry et al. (US 2003/0059902; hereinafter R2) and Watanabe et al. (2003, Cloning, Expression and cell surface localization of *Paenibacillus* sp.; hereinafter R3)

3. R1 discloses a variant xylanase polypeptide, or fragment thereof having xylanase activity. (Abstract).

4. R1 discloses that xylanases of Family 11 are of interest in baking. (page 10, lines 8-12). R1 discloses polypeptides prepared by recombinant means (pages 14-15).

5. R1 discloses the transformation of host cells and/or host organisms. (page 25, line 34 to page 26, line 31).

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6. R1 discloses the applications of the xylanases of their invention in food and feeds. R1 teaches of the application of the xylanases of their invention in the preparation of dough and baked products obtained by baking such a dough and in the preparation of noodle and pasta products. (page 32, lines 7-34).

7. R1 is silent regarding the addition of exo-acting maltogenic amylase to the dough. R1 is also silent regarding the *Paenibacillus* xylanase as presently claimed.

8. R2 discloses that the maltogenic alpha-amylase variants of the invention have properties that can retard or prevent retrogradation, and thus the staling of starch based food common in the baking industry. The variant can be used for the preparation of bread and bread products per techniques known in the art. The maltogenic enzyme can be used on its own or in combination with additional enzymes including xylanase. [0131-0134]. Therefore, it is clear that application of maltogenic amylase together with xylanase, as presently claimed, was known in the art at the time the invention was made. Therefore, their incorporation into dough would be expected to bring about desirable dough and bread properties.

9. R2 is silent regarding the *Paenibacillus* pabuli xylanase.

10. R3 discloses the cloning, and expression of xylanase from *Paenibacillus* sp. strain w-61(The whole article).

11. R3 discloses that this organism was formerly known as *Aeromonas caviae* W-61. R3 designates *Paenibacillus* sp. W-61 to this organism. It is also noted that the xylanase from *Aeromonas caviae* W-61 was also known at the time of this invention. (Applicants can refer to Viet et. al. 1991. Appl. Environmental Microbiol. 57:444-449).

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This xylanase has 96.7% identity to the amino acid sequence of Seq. ID No. 2 as presently claimed.

12. Therefore, the presently claimed xylanase from *Paenibacillus* sp. was known in the art at the time the invention was made. Since R1 discloses the incorporation of xylanase enzymes to improve the baking properties of bread, the inclusion of the known *Paenibacillus* xylanase, in dough, showing such a close identity to the claimed xylanase would have been expected to demonstrate the same properties regarding the improvement of bread crumb and loaf volume and thus obvious to an artisan.

13. Since the claimed xylanase was known, its incorporation into dough would have produced the same results as the presently claimed xylanase regarding the freshness of bread crumb. Regarding the amino acid and nucleic acid sequences as presently claimed, R3 discloses the cloning and expression of a recombinant xylanase. R3 discloses that based on the N-terminal amino acid sequence of the xylanase, primers (forward and backward) are synthesized and the amplification of the gene is done by polymerase chain reactions (PCR). R3 then clearly discloses that the amplified fragment is inserted into specific sites of a known plasmid. R3 also discloses the hybridization process in that the cloned fragment is digested with a known restriction enzyme (HindIII) and the resulting smaller fragment (0.9 kbp) which is located in the larger fragment (1.8 kbp) is used as a probe for DNA hybridization. The hybridization procedure is done per established methods in the art as disclosed by R3. R3 then discloses the transformation of *E. coli* cells carrying the xylanase gene. The ampicillin resistance is used as the marker for the transformed *E. coli* cells. The culture medium for growing the

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transformed cells as well as the purification of the recombinant xylanase and the determination of the N-terminal sequence of the purified enzyme are disclosed by R3.

The expressed enzyme, as shown by R3, functions as an endo-xylanase capable of hydrolyzing  $\beta$ -1,4 glycosidic bonds in oat xylans. Therefore, it is expected that the recombinant xylanase functions as the native enzyme regarding the hydrolysis of xylans. On the other hand, since *Paenibacillus* sp. was known to possess xylanolytic enzyme, strains having this potential would have been screened out following standard methods in the art. Once the candidate is screened out, the enzyme would have been purified and cloned as disclosed by R3. The ultimate incorporation of either the native or the recombinant enzyme into dough to improve baking properties was motivated by R1 therefore, its utilization in baking would have been obvious and within the skill of the art.

14. Compositions comprising xylanase and flour as presently claimed are also known in the art. Such compositions could be in powder, granulate or liquid form which are all known in the art.

15. Therefore, it would have been obvious to those of skill in the art, at the time the invention was made, to prepare xylanase(s) from *Paenibacillus pabuli*, including the presently claimed strain, and clone it in host cells of e.g. *E. coli*, as disclosed by R3, culture the transformed host cells per methods of R3, ultimately recover the enzymes from the cell free extract of the host cells and apply the enzyme (In pure or partially purified forms) in baking as disclosed by R1. One would do so to take advantage of the xylanase enzyme of a specific source in baking and expect to observe the improvement in bread crumb and loaf volume as disclosed by R1. Absent any evidence to contrary

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and based on the combined teachings of the cited references, there would be a reasonable expectation of success to screen for xylanase producing *Paenibacilli*, and clone it in suitable host cells for over-expression of the enzyme and ultimately apply the enzyme in baking.

### ***Response to Arguments***

Applicants' arguments have been reviewed. These arguments are not persuasive for the following reasons.

1. Applicants argue that none of R1, R2 and/or R3 teach or suggest the use of a xylanase in preparing dough based product, in a flour composition or in a granulate wherein the xylanase has at least 90% identity to Seq. ID No. 2.

a. R3 clearly discloses that the *Paenibacillus* strain W-61 is in fact *Aeromonas caviae* W-61. A xylanase from *Aeromonas caviae* W-61 was known in the art which has 96.7% identity to the Seq. ID. No. 2 which is presently claimed. Being a xylanase, its purification, cloning, recovery and incorporation into a dough, as disclosed by R3 and R1, would have been obvious.

While the utilization of a xylanase having at least 90% identity to SEQ. ID. NO.2 in dough making and baking is not disclosed by R1, R2 or R3, looking for a known xylanase source, screening out a specific strain, characterizing the enzyme, cloning of the enzyme, expressing the enzyme and ultimately using it in baking, for the same purpose as disclosed by R1, would have been obvious to those of skill in the art.

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2. Applicants argue that Example 3 of the instant specification increases the amount of free water, which has been described in the literature to correlate to moistness of bread crumb, more than prior art xylanase.

a. It is noted that this feature is not reflected in the claimed invention. However, since the xylanase from *Paenibacillus* sp. W-61 (formerly *Aeromonas caviae* W-61) was known in the art, at the time of the invention, its incorporation into dough would have been obvious per teachings of R1. Having 96.7% identity, as disclosed by R3, to Seq. ID. No. 2, this enzyme would have resulted in the same increase in the amount of free water as disclosed in Example 3., therefore, the moistness of bread crumb produced with the xylanase of R3 and the xylanase as presently claimed would have been expected to be the same.

### **Conclusion**

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R. Badr  
Examiner  
Art Unit 1781

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1781